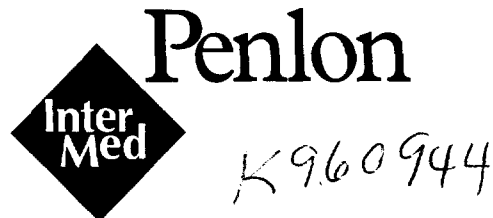


Your Ref:

Our Ref:



ATTACHMENT 5

APR - 2 1990

Penlon Limited

Radley Road
Abingdon
Oxon OX14 3PH

Telephone: Abingdon (01235) 554222

Fax: (01235) 555252

Sales Fax: (01235) 555900

Telex Agency: 826715 AERO G

Cables: Penlon Abingdon

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, and in connection with our supplement in respect of the Penlon PPV Vaporizers.

1. Compliance With Standards

We confirm that sample vaporizers have been subjected to the tests listed in ASTM F1161:1988 Clause 12, and have been shown to comply with this standard. We also confirm that the test equipment and test conditions used complied with Clause 4 of this standard.

The User Manual has been examined and contains the information required by the above standard.

2. An appendix to the hazard analysis has been performed on the design, based on study of literature and evaluation reports, together with in-house experience covering more than 30 years' manufacture and marketing of vaporizers.
3. The test work to show compliance with ASTM F1161:1988 Clause 12 has been extended to cover the external influences noted during the hazard analysis appendix and the results are incorporated as **WARNINGS, Caution** or Information in the User Manual
 - (a) Vaporizer filling instructions clarification 12.1.13
4. Incorrect and overfilling protection is provided by the combination of (a) an air lock; (b) agent specific fillers; (c) level indicator with visual indication; (d) an overspill passage open during filling.

. . . /2

Attachment 5 cont'd

We certify that this summary only includes information which is included in the 510(K) supplement submission.

for PENLON LIMITED

A handwritten signature in black ink, appearing to read "Alan C Green". The signature is written in a cursive, flowing style.

Alan C Green
Technical Director